UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,635	10/17/2003	Germaine Zocchi	F1584	1961

7590 02/21/2006

Colgate-Palmolive Company
909 River Road
P. O. Box 1343
Piscataway, NJ 08855-1343

EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,635	ZOCCHI, GERMAINE	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt amendment and remarks filed 11/28/05. Claims 1-3 are pending.

Claim Rejections - 35 USC § 103

1. Claims 1-3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Leahy et al. (US 6,281,1920).

Applicants argue:

a) Leahy discloses compositions for treating symptoms of dry eyes.

b) Leahy does not discloses very small amounts of preservatives including polyhexamethylene biguanide at 15 ppm and there is no suggestion in Leahy to select biguanide in preference to the any of the other preservatives.

c) Leahy does not provide suggestion to increase the amounts of the amounts to the claimed levels since increased amounts would have no obvious benefit in the treatment of dry eyes.

d) That obviousness rejection cannot be based on picking and choosing from among the "numerous choices and then changing the amount of the selected component."

2. Applicant's arguments filed 11/28/05 have been fully considered but they are not persuasive.

Regarding a), it is noted that the instant claims are directed to compositions and future intended uses of compositions are not accorded patentable weight. A recitation of the intended

use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding b), there is no demonstration that the recited amounts have unexpected results over the disclosed amounts of the polyhexamethylene biguanide; a selection of polyhexamethylene biguanide is not required because Leahy specifically discloses composition that contains polyhexamethylene biguanide as seen in Example 9, Table X and Example 10, Table XI. And thus,

Regarding d), a picking and choosing is not required or necessary since specific compositions contain the polyhexamethylene biguanide (see Example 9, Table X and Example 10, Table XI).

Regarding c), applicant provided no factual evidence of the claimed amount vs the disclosed amount of the polyhexamethylene biguanide showing differences between the claimed amounts and the amounts disclosed in Leahy; and in the absence of factual evidence, the claimed amount of polyhexamethylene biguanide does not patentably distinguish over the disclosed amount when and generally, differences in amounts of the disintegration agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount is critical. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The claims are directed to compositions. The rejection is reproduced below.

Leahy discloses a composition comprising mucin, Xanthan gum, buffering agents, tonicity agents, humectant, wetting agents (surface active agents) and preservatives; polyhexamethylene biguanide is a preservative; TETRONIC, PLURONIC and the polyethyleneoxide-polypropyleneoxide block copolymers are surfactants (column 8, lines 10-67); Xanthan gum is a viscosity agent and also anionic biopolymer. The contact lens formulation (Table XI, Example 10, formulation A and B) shows a formulation comprising 0.5% Tetronic, 15 ppm polyhexamethylene biguanide, 1% mucin for formula A and 2% mucin for formula B. Water is part of the composition. See also claims 1-25.

The 1% and 2% mucin meets the limitation of 0.1% to 5% generic anionic polymer or mucin (claims 1 and 2). The 0.5% Tetronic meets the limitation of 0.01 to 5 wt% surfactant recited in claim 3. Thus, Leahy discloses the instant composition. Future intended use, in this case antimicrobial has no patentable weight in a composition claim. However, also, since the instant composition and the composition of the prior art contain the antimicrobial agent, polyhexamethylene biguanide, both compositions must exhibit the same property and the property of a composition is not separable from the composition. The comprising language of the instant claims is open.

Leahy discloses the instant composition. Leahy differs in the amount of the biguanide. But, there is no demonstration in applicant's specification showing that the recited amount of the biguanide provides unexpected and unusual results. Generally, differences in amounts of the antimicrobial agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results or unusual results. "W[here] the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation according to Leahy. One having ordinary skill in the art would have been motivated to use the appropriate amount of the antimicrobial agent, which in combination with the surfactant and the anionic biopolymer would produce a composition that have the desired antimicrobial properties.

3. Claims 1 and 3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (US 6,277,365) or Tetsuhisa et al. (JP 2000-109892, Computer translation).

Applicant agues:

e) Polyhexamethylene biguanide is mentioned an antimicrobial agent in Ellis in composition that is used to treat eyes, that the amount in Ellis is much less than that claimed, that there is no motivation to in Ellis to change increase the amount of the polyhexamethylene biguanide and that the arguments presented for Leahy applies to Ellis.

f) That Tetsuhisa discloses ophthalmic composition that uses germicides at up to 0.1% biguanide with 0.001% as the preferred amount in paragraph [0009] of the Tetsuhisa translation.

4. Applicant's arguments filed 11/28/05 have been fully considered but they are not persuasive.

Regarding e), test solution of Example 4 of Ellis contains polyhexamethylene biguanide; and applicant provided no factual evidence of the claimed amount vs the disclosed amount of the

polyhexamethylene biguanide showing differences between the claimed amounts and the amounts disclosed in Ellis; and in the absence of factual evidence, the claimed amount of polyhexamethylene biguanide does not patentably distinguish over the disclosed amount when and generally, differences in amounts of the disintegration agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount is critical. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The claims are directed to compositions. The rejection is reproduced below. The claims are directed to compositions and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding f), it is noted that while Tetsuhisa in paragraph [0009] of the translation discloses a desirable amount of 0.001%, Tetsuhisa claims amount of 0.00001-0.1% and also specifically claims polyhexamethylene biguanide (claims 3-5 of Tetsuhisa).

The rejections over Ellis and Tetsuhisa are including below.

Ellis discloses composition comprising 0.00001 to about 5 wt% of antimicrobial agent of which is polyhexamethylene biguanide hydrochloride; the composition also contains 0.015% xanthan gum; 0.015% GLUCQUAT 100 glycoside as surfactant in Example 1. Hyaluronic acid is disclosed in Example 3. However, in Test Solution 2, Ellis uses 15 ppm polyhexamethylene biguanide, 0.01% surfactant, and 0.3% xanthan gum. See also abstract; column 2, lines 40-45

and 54-67, columns 5 and 6 and claims 1-26. The 15 ppm is less than that required in the claims. The amount of the surfactant and the anionic biopolymer (hyaluronic acid or xanthan gum) meet the limitation of the amounts in the claims. Thus the difference between the claims and the prior art is in the amount of the biguanide antimicrobial agent. The composition contains water. Future intended use provides no patentable distinction to composition claims. In the instant case, both the composition of the prior art and the composition of the claimed invention have the same ingredients and would therefore have the same antimicrobial properties from the biguanide and the surfactant. The comprising language of the claims is open. Generally, differences in amounts of the antimicrobial agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results or unusual results. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). And there is no demonstration in applicant's specification showing that the recited amount of the biguanide provides unexpected and unusual results

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation according to Ellis. One having ordinary skill in the art would have been motivated to use the appropriate amount of the antimicrobial agent, which in combination with the surfactant and the anionic biopolymer would produce a composition that have the desired antimicrobial properties.

Tetsuhisa discloses a composition that comprises 0.001-10 wt% chondroitin sulfate and/or hyaluronic and polyhexamethylene biguanide or salt thereof (abstract). The

concentration of the biguanide or ammonium chloride derivative is 0.00001-0.1% (claims 1-5) and specifically discloses that the preferred concentration of the biguanide is from 0.00001-0.001% (see detailed description section at page 3, which concentration duffers from the claimed concentration. The composition also contains surfactants (claim 6) and the amount of the surfactant is from 0.1-5%, and preferably 0.01-10% (page 3 of detailed description section), and this meets the limitation of the claimed amount. The composition contains water.

Thus, Tetsuhisa discloses the claimed composition and the difference between the claims and the prior art is in the amount of the biguanide antimicrobial agent. Future intended use provides no patentable distinction to composition claims. In the instant case, both the composition of the prior art and the composition of the claimed invention have the same ingredients and would therefore have the same antimicrobial properties from the biguanide and the surfactant. Generally, differences in amounts of the antimicrobial agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results or unusual results. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). And there is no demonstration in applicant's specification showing that the recited amount of the biguanide provides unexpected and unusual results

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation according to Tetsuhisa. One having ordinary skill in the art would have been motivated to use the appropriate amount of the antimicrobial

agent, which in combination with the surfactant and the anionic biopolymer would produce a composition that have the desired antimicrobial properties.

Double Patenting

5. Claims 1 and 3 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,479,044.

6. Claims 1 and 3 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/224,692.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's request to defer the rejection is not persuasive and MPEP 804 1B states "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

If the "provisional" double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the

application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection, which will be converted into a double patenting rejection when the one application issues as a patent."

Thus the rejections are maintained --- no allowable subject matter.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tsao Fu-Pao (US 5,858,996) discloses ophthalmic composition comprising mixture of polyhexamethylene biguanide and hyaluronic acid among others (column 3, lines 52, 61 and 62 and claim 5. Jampani et al. (US 5,980,925) discloses a wash solution comprising hyaluronic acid and polyhexamethylene biguanide (column 3, line 2; column 5, line 11; column 4, line 62); the antimicrobial agent is present in amounts of 0.01 to 10%, preferably 0.01 to 5% and more preferably 0.1 to about 2% (column 3, lines 43-45). Policicchio et al. (US 6,910,823 B2) discloses cleaning composition (abstract).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

MICHAEL HARTLEY
PRIMARY EXAMINER